

K123814

3. 510(k) Summary

Prepared On: December 10, 2012

Applicant / Sponsor: Fx Solutions
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01440 Viriat
France

Manufacturer: Compagnie Financière & Médicale
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France

Contact: Jean-Jacques Martin
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Proprietary Name: Humelock II Cemented Shoulder System

Common Name: Total and Hemi-Shoulder Replacement System

Classification Names: 21 CFR 888.3650: Shoulder joint metal/polymer non
constrained cemented prosthesis, Class II

21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder)
metallic uncemented prosthesis, Class II

Product Codes: KWT, HSD

Substantially
Equivalent Devices: K111097 – Fx Solutions Humelock Cemented Shoulder
Prosthesis

K060874 – DePuy Global AP Shoulder System

AUG 13 2013

Device Description:

The Humelock II Cemented Shoulder System is a total and hemi-shoulder prosthesis consisting of a humeral stem, a humeral head, a double taper connector and, when used for total shoulder replacement, a glenoid component.

The humeral stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and is available in diameters of 6-15mm. The distal end of the humeral stem is cylindrical with a polished surface. The proximal portion of the humeral stem has a grit blasted surface.

The humeral stem incorporates a female taper for attachment of the double taper connector, which connects to the humeral head.

The double taper connector is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3. One size is available and is compatible with all sizes of humeral stems and humeral heads. The double taper connector has a male taper on each end and is used to connect the humeral head to the humeral stem. An impactor / extractor hole is incorporated into the proximal end of the taper.

The humeral head is manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and is available in diameters of 39 – 54mm in centered and offset styles. The offset of the taper allows the head to be rotated relative to the cut surface of the humerus to provide optimal coverage of the bone. A female taper allows attachment to the double taper connector, which connects to the humeral stem.

The glenoid component is manufactured from ultra high molecular weight polyethylene (UHMWPE) conforming to ISO 5834-2. It is available in sizes extra small, small, medium, large and extra large. The glenoid component features two pegs for cemented fixation to the glenoid bone. Each peg contains a radiopaque marker manufactured from tantalum conforming to ASTM F560.

Intended Use / Indications:

The Humelock II Cemented Shoulder System is indicated for use in total and hemi-shoulder replacement to treat:

1. Proximal humeral fractures
2. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a previously implanted primary component, a humeral plate or a humeral nail).

The humeral stem and glenoid components of the Humelock II Cemented Shoulder System are intended for cemented use only.

K123814

Summary of Technologies/Substantial Equivalence:

Substantial equivalence of the Humelock II Cemented Shoulder Prosthesis to the predicate devices is based on a comparison of indications, intended use, materials, design and sizing, and mechanical testing.

Non-Clinical Testing:

Mechanical testing was conducted to demonstrate the stability of the modular connection between the double taper connector and the humeral stem. Pull off testing of the humeral head from the taper was conducted previously. Characterization data was provided for the UHMWPE used to manufacture the glenoids.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Humelock II Cemented Shoulder System and the predicate shoulder systems.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 13, 2013

Mr. Jean-Jacques Martin
Managing Director
Fx Solutions
1663 rue de Majornas
Viriat, 014440 France

Re: K123814

Trade/Device Name: Humelock II Cemented Shoulder System
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, HSD
Dated: July 1, 2013
Received: July 2, 2013

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K123814

Device Name: Humelock II Cemented Shoulder System

Indications for Use:

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Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR **Over-The-Counter Use** _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 7 of 7

Elizabeth Frank-S

Division of Orthopedic Devices